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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,334	11/25/2003	Giovanna Galli	141483.00005-P1255US00	6523

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,334	GALLI ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 Aug 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed August 31, 2006. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The disclosure is objected to because of the following informalities: there are several typos throughout the disclosure such as it is believed "cetylpiridinio chloride" should read "cetylpyridinium chloride". It is suggested that the specification should be reviewed to correct additional possible spelling and grammar errors.

Appropriate correction is required.

Claims

Election by Original Presentation

Newly submitted claim 14 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 14 is drawn to a method of preventing and treating oral cavity diseases whereas the original claims are drawn to a composition for preventing and treating oral diseases. If claim 14 were originally presented, the claims would have been restricted as follows:

1) Claims 1-13 drawn to a composition for treating oral cavity diseases class 424, subclass 49.

2) Claim 14 drawn to a method of treating oral cavity diseases class 514, subclass 900.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 14 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112 – New Matter

Claims 1, 4-5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the phrase "a minimum 3 days up to 10 days". The specification recites "typically three to ten days" (paragraph 0051). It is suggested Applicant use the "three to ten days" to avoid ambiguity.

Claim Rejections - 35 USC § 112 – Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating oral diseases, does not reasonably provide enablement for preventing oral diseases. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention,
2) the breadth of the claims
3) the relative skill of those in the art,
4) the state of the prior art,
5) the predictability of the art,
6) the amount of direction or guidance provided,
7) the presence or absence of working examples, and
8) the quantity of experimentation necessary,

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

1) *The nature of the invention.* The invention discloses using a composition comprising a therapeutic agent, which is soluble in both water and alcohol, and a biocompatible polymeric material to treat oral diseases.

2) *The breadth of the claims.* The claims are broad because they read on "preventing".

3) *The relative skill of those in the art.* The relative skill of those in the art are PhD, MD, and MS.

4) *The State of the Prior Art.* The prior art discloses that using therapeutic agents such as antibacterials, dentinal desensitizing agents, antivirals and antibiotics are used to treat oral cavity diseases.

5) *The Predictability or Lack Thereof in the Art.* Prevention is not practical with oral diseases due to the unpredictability of the condition and prevention reads on "cure". According to the American Dental Association (http://www.ada.org/public/topics/bad_breath.asp), oral diseases can be caused by health problems (such as diabetes) or lack of getting the oral cavity professionally cleaned. Periodontal disease begins with plaque that is not removed during daily cleaning. When plaque is not removed it turns into calculus. It is impossible to remove all calculus with daily brushing (http://www.perio.org/consumer/faq_general.htm, pages 1-4). The calculus, if untreated, causes gingivitis, the first stage of periodontal disease. Therefore it is likely a small amount of gingivitis is present in between dental visits. In the case of conditions such as halitosis, it may be caused by dry mouth, tobacco products or medical disorders such as liver or kidney ailments. In the case of the instant invention, periodontal disease can be caused by different factors, therefore it is nearly impossible to protect against them all with one compound or mouthwash solution.

6) *The Amount of Direction or Guidance Present.* The specification discloses compositions encompassing the instant claims but does not specify the ailments the individual compositions may be used to treat. This guidance or lack thereof is not commensurate with the full scope of the claims.

7) *The Presence or Absence of Working Examples.* The examples in the specification are examples of compositions. There is a lack of examples using the compositions to treat patients with oral diseases or examples where the compositions prevent oral diseases from occurring.

8) *The Quantity of Experimentation Needed.* The applicant needs to provide examples of using the compositions on patients that are likely to develop oral diseases due to health problems, tooth extraction or genetic factors. Other experiments include using the compositions on patients who have had oral diseases and no longer have them, and show that they do not develop the disease or conditions related to the disease again. The applicant also needs to provide experiments that show once the compositions are used the diseases no longer occur.

Suggested language. Since the term "treating" is a broad term, it will inherently cover therapies in which some protective function may also be present. Accordingly, the examiner recommends simply reciting a composition for "treating" oral cavity diseases.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 1, 4-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (US 5,160,737).

Friedman et al. disclose liquid polymer compositions to treat dental and dermatological conditions. The compositions comprise a liquid methacrylic acid copolymer and a pharmacological agent. The compositions form a film upon drying and releases the pharmaceutical agents over a period of time. Several polymer

combinations were disclosed within the reference, a composition with Eudragit RL, one with Eudragit RS and one with a combination of Eudragit® RL and Eudragit® RS, which encompasses claim 1. The general procedure for making the polymer solutions included dissolving the polymer and therapeutic agent, cetylpyridinium chloride, in ethanol. After complete dissolution of these ingredients, additional components in aqueous solution were added, while continuously stirring. The ratio of film components to solvents (water/alcohol) was 1:3. In the water containing examples, the water makes up about 19% of the compositions (see example 19), which encompasses claim 4. Several therapeutic agents may be incorporated into the compositions, e.g., antibacterials chosen from the penicillins and ampicillins, erythromycin, tetracycline, clindamycin and chloramphenicol (which encompasses claim 8); antiseptics, chlorhexidine and cetylpyridinium chloride; and hypersensitivity agents, potassium chloride and strontium salts, as recited in claim 5. These compounds are commercially available their pharmaceutical salts[1]. The effective time period for release of the drug comprised in the compositions is one hour or longer to as much as 2 to 4 weeks, which encompasses 3 to 10 days. This indicates the compositions of the reference can be adjusted to meet the required drug release time period. In regards to selecting a drug that is soluble in both water and alcohol, some of the drugs disclosed by the reference are some of the drugs disclosed by the instant claims, therefore it is concluded that

[1] Clindamycin and chloramphenicol are commercially available as their water soluble salt clindamycin Palmitate (http://www.webmd.com/drugs/drug-13718-Clindamycin+Palmitate+Oral.aspx?drugid=13718&drugname=Clindamycin+Palmitate+Oral), Chloramphenicol sodium succinate (http://www.rxlist.com/cgi/generic3/chloramphenicol.htm) and piperacillin sodium (http://www.rxlist.com/cgi/generic3/piperacillin.htm).

these drugs are both soluble in water and in alcohol. The reference differs from the instant claims insofar as it does not specifically disclose the agent is released from the film over a period of a minimum of 3 days to 10 days.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the compositions of the primary reference accordingly motivated by the desire to obtain the desired release rate of the agent from the formed film, as supported by cited precedent.

2) Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (US 5,160,737) in view of Mantelle et al. (US 6,562,363).

The primary reference, Friedman et al., is discussed above. The reference differs from the instant claims insofar as it does not teach piperacillin as one of the antibacterials used in the compositions.

Mantelle et al. disclose bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes comprising a composition which results from an admixture of at least one PVP polymer, at least one bioadhesive and optionally a pharmaceutically acceptable solvent suitable for use with an active agent. The bioadhesive composition can either include an active agent incorporated directly in the composition, or a separate source of an active agent (see abstract). The pressure-

sensitive adhesives that may be used in the compositions include acrylic adhesives, e.g., Eudragit® RS and RL. Eudragit® RS100 was used in Examples 79, 81 and 83, which also comprised dipropyleneglycol, making the composition a liquid composition as recited by the instant claims. The active agents that may be used in the delivery systems of the disclosed reference include antibacterial agents such as piperacillin[1]. The disclosed compositions can be prepared by mixing the one or more bioadhesives, in powder or liquid form, PVP and active agent, with or without a pressure-sensitive adhesive, preferably in an appropriate volatile, lower molecular weight solvent. When a pressure-sensitive adhesive is used, preferably the volatile, lower molecular weight solvent is an organic solvent supplied with the pressure-sensitive adhesive, for example, the acrylic adhesive. The reference differs from the instant claims insofar as it does not disclose the time of release for the drug is 3 to 10 days.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See* Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have delivered piperacillin using the compositions of the primary reference motivated by the desire to deliver the antibacterial drug to the targeted area for its known function as supported by case law.

Claims 1, 4-5 and 8 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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